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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/143,828	08/31/1998	ANDERS BERKENSTAM	10806-65	4054

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
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GROTON, CT 06340

EXAMINER	
PAK, MICHAEL D	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/143,828	BERKENSTAM ET AL.	
	Examiner	Art Unit	
	Michael Pak	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,13-17,51-58,60 and 62-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *2,51 and 53* is/are allowed.

6)☒ Claim(s) *1,13-17,52,54-58,60 and 62-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The indicated allowability of claims 1-2, 13-17, 51-58, 60, and 62-80 is withdrawn in view of the newly discovered reference(s) to Evans et al. (US 6,756,491). Rejections based on the newly cited reference(s) follow.

Response to Amendment

2. Amendment filed 1 December 2004 has been entered. Claims 1-2, 13-17, 51-58, 60, and 62-80 are pending.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

4. Applicant is advised that should claims 13-17, 56-58, and 62, be found allowable, claims 64-73 and 78-80 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

5. Claims 16-17, 54-55, 71-72 and 79-80 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the fulfilling the preamble stated purpose of recombinant production of a polypeptide which includes steps such as transfecting culturing the cell and producing the polypeptide.

6. Claims 14, 52, and 69 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated cells transfected or transformed with an expression vector, does not reasonably provide enablement for an isolated cell comprising nucleic acid which is not contained in a vector. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The first paragraph of § 112 requires that the patent specification enable "those skilled in the art how to make and use the full scope of the claimed invention without `undue experimentation.'" Genentech, Inc. v. Novo Nordisk AIS, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)); see also In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). ("[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art."). Whether making and using the invention would have required undue experimentation, and thus whether the disclosure is enabling is a legal

conclusion based upon several underlying factual inquiries. See In re Wands, 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988). As set forth in Wands, the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Likewise, in Amgen Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), the court affirmed the holding of invalidity of claims to analogs of the EPO gene under § 112 for lack of enablement where applicants had claimed every possible analog of the EPO gene but had disclosed only how to make EPO and a very few analogs. "[D]espite extensive statements in the specification concerning all analogs of the EPO gene that can be made, there is little enabling disclosure of the particular analogs and how to make them .... There may be many other genetic sequences that code for EPO-type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them." Id., 927 F.2d at 1213-14, 18 USPQ2d at 1027.

Claims encompass isolated cells comprising heterlogous nucleic acid, which has not been placed in a vector. However, one skilled in the art cannot make and use isolated cells, which are transfected or transformed with nucleic acid, which is not in a vector. The state of the art is such that one skilled in the art places the desired nucleic

acid in a vector prior to transfecting or transforming a cell (Evans et al., US 6,756,491, column 13-16). The amount of direction provided in the specification is limited to what is practiced by one skilled in the art, which is to transfect using nucleic acid, subcloned into a vector. The nucleic acid without a vector, which is transfected into a cell, will be lost during cell division without a selective pressure provided by the vector. One skilled in the art would require empirical experimentation in order to determine how to transform or transfect heterologous nucleic acid without a vector. Such experimentation is unpredictable and requires undue experimentation. Therefore, based on the above Wands analysis, a preponderance of the evidence supports a conclusion that one skilled in the art would not have been enabled to make and use the claimed invention without undue experimentation.

7. Claims 16-17, 54-55, 71-72 and 79-80 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process for recombinant production of a polypeptide comprising culturing an isolated host cell comprising the expression vector comprising the desired nucleic acid and producing the polypeptide, but does not reasonably provide enablement for the claimed process which only expresses the nucleic acid in a host cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The first paragraph of § 112 requires that the patent specification enable "those skilled in the art how to make and use the full scope of the claimed invention without

`undue experimentation.'" Genentech, Inc. v. Novo Nordisk AIS, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)); see also In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). ("[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art."). Whether making and using the invention would have required undue experimentation, and thus whether the disclosure is enabling is a legal conclusion based upon several underlying factual inquiries. See In re Wands, 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988). As set forth in Wands, the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Likewise, in Amgen Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), the court affirmed the holding of invalidity of claims to analogs of the EPO gene under § 112 for lack of enablement where applicants had claimed every possible analog of the EPO gene but had disclosed only how to make EPO and a very few analogs. "[D]espite extensive statements in the specification concerning all analogs of the EPO gene that can be made, there is little enabling disclosure of the particular analogs and how to make them .... There may be many other

genetic sequences that code for EPO-type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them." Id., 927 F.2d at 1213-14, 18 USPQ2d at 1027.

Claims encompass a process for recombinant production with only the steps of expressing the nucleic acid in a host cell. However, one skilled in the art cannot produce the polypeptide without culturing an isolated host cell comprising the expression vector comprising the desired nucleic acid and producing the polypeptide. The state of the art is such that one skilled in the art produces the polypeptide by placing the desired nucleic acid in an expression vector prior to transfecting or transforming a cell, culturing the cell, and producing the polypeptide in the cell (Evans et al., US 6,756,491, column 13-16). The amount of direction provided in the specification is limited to what is practiced by one skilled in the art which is placing the desired nucleic acid in an expression vector prior to transfecting or transforming a cell, culturing the cell, and producing the polypeptide in the cell. Without such steps the polypeptides are not produced. One skilled in the art would require empirical experimentation in order to perform the polypeptide production with a single step. Such experimentation is unpredictable and requires undue experimentation. Therefore, based on the above Wands analysis, a preponderance of the evidence supports a conclusion that one skilled in the art would not have been enabled to make and use the claimed invention without undue experimentation.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, the applications upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-2, 13-17, 51-58, 60, and 62-80 of this application. See MPEP 706.02. Claims rejected above under 35 U.S.C. 112 does not receive benefit of priority for the reasons set forth in the above rejection. Claims 1, 13-17, 56-58, 60, 63-65, 68-75, and 78-80 do not receive priority of the specific claim limitations drawn to the specific amino acid residue numbers "39 to 115 or 141 to 434 of SEQ ID NO:2." The only support for the specific residue numbers can only be found in the current application in figure 12, which is not present in the parent applications. Claims 1-2, 13-17, 51-58, 60, and 62-80 receive priority for the utility and enablement of the receptor for the foreign priority SE 9801148-9 because the prior parent applications 60/067,373 and SE 9703745-1 do not disclose the function of the orphan receptor.

Claim Rejections - 35 USC § 102

8. Claims 1, 13-17, 56-58, 60, 63-65, 68-75, and 78-80 are rejected under 35 U.S.C. 102(e) as being anticipated by Evans et al.(US 6,756,491).

Evans et al. discloses nucleic acid encoding steroid X receptor (SEQ ID NO:2) which has 100% amino acid sequence identity with the claimed SEQ ID NO:2 (column 3-6). Evans et al. discloses vectors and cells comprising the nucleic acid and the method of producing the protein with the transfected cell (columns 9-10).

9. Claims 2, 51 and 53 are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (571) 272-0879. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael D. Pak

Michael Pak
Primary Patent Examiner
Art Unit 1646
29 January 2005